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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,095	11/18/2003	Alexandra Kaczmarek	21489	5755

151 7590 07/31/2007

HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
07/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,095	KACZMAREK ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *6-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 23 April, 2007. Claims 1-11 are pending in the instant application. Claims 6-11 have been withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Claims 1-5 are currently under examination.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hoess *et al.* (2003)[1] in view of Wagner *et al.* (1995). As previously set forth, Hoess and colleagues provide a process for making antifusogenic polypeptides employing inclusion bodies, denaturing agents, solubilizing agents, and cleavage of the peptide to obtain said antifusogenic polypeptide. This teaching does not disclose constructs

[1] Hoess *et al.* (2003) has an effective filing date of 30 May, 2002, which precedes applicants' earliest effective filing date.

comprising repeating peptide units. Wagner and associates provide multicopy polypeptide constructs that are efficient for the expression and purification of recombinant proteins. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to prepare multicopy polypeptide constructs, as suggested by Wagner *et al.* (1995), from the constructs of Hoess *et al.* (2003), since this would increase the production of the antifusogenic polypeptide of interest thereby making more available for diagnostic and pharmaceutical applications. Both a reasonable expectation of success and the motivation to do were present in the prior art at the time of filing.

Applicants traverse and submit that motivation to combine and expectation of success must be founded in the prior art, not the applicants' disclosure. See *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). It was further noted that the prior art must suggest the desirability of making any given modification. Specifically, applicants argue that neither reference, either alone or in combination, render the claimed invention *prima facie* obvious. Applicants are reminded that there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276, 69 U.S.P.Q.2d 1686, 1690 (Fed. Cir. 2004). While the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988) and

In re Jones, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992). Moreover, applicants are further reminded that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 U.S.P.Q. 209 (C.C.P.A. 1971).

Contrary to applicants' assertions, Hoess and colleagues clearly provide a process for the production of an **antifusogenic peptides** by producing fusion peptides with a length of about 14 to 70 amino acids in **prokaryotic host cells**, comprising the steps, under such conditions that **inclusion bodies** of said fusion peptide are formed, of: (a) expressing in said host cell a nucleic acid encoding said fusion peptide consisting of a first peptide which is an **antifusogenic peptide** of a length of about 10 to 50 amino acids and a second peptide of a length of about 4 to 30 amino acids, said first peptide being N-terminally linked to said second peptide; (b) cultivating said host cell to produce said **inclusion bodies**; and (c) **recovering said antifusogenic peptide from said inclusion bodies**, wherein said recovered antifusogenic peptide consists of said fusion peptide or a peptide comprising the antifusogenic peptide of about 10 to 50 amino acids and which is a fragment cleaved from said fusion peptide. Inclusion bodies of the peptides are disclosed. Also disclosed is a nucleic acid encoding the fusion peptide consisting of a first peptide which is an antifusogenic peptide. This teaching provides detailed methodologies for obtaining and solubilizing said peptides from inclusion bodies. Thus, the only limitation of this teaching is that it does not disclose

the utilization of repeat polypeptide units. However, this deficiency is clearly compensated for by Wagner and associates who clearly provide **multicopy polypeptide constructs** that are efficient for the expression and purification of recombinant proteins. Thus, the skilled artisan would have clearly been motivated to make multicopy polypeptide constructs comprising a an antifusogenic polypeptide and employ a prokaryotic inclusion body expression system since this represents a rapid and facile means for obtaining large quantities of active, purified recombinant products.

Finality of Office Action

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the

examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing Sys tem. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

23 July, 2007